

ERNEST ORLANDO LAWRENCE BERKELEY NATIONAL LABORATORY

A3054-01

Animal Welfare Assurance for Domestic Institutions

I, Horst Simon, PhD, as named Institutional Official for animal care and use at Ernest Orlando Lawrence Berkeley National Laboratory (LBNL) provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS. This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
This Assurance covers the entire Institution; there are no branches or subcomponents.
- B. The following are other institution(s), or branches and components of another institution:
This Assurance covers the entire Institution; there are no branches or subcomponents.

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.

Recommended Reference:

- o [Distribution of Assurance within Institution](#)

- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).

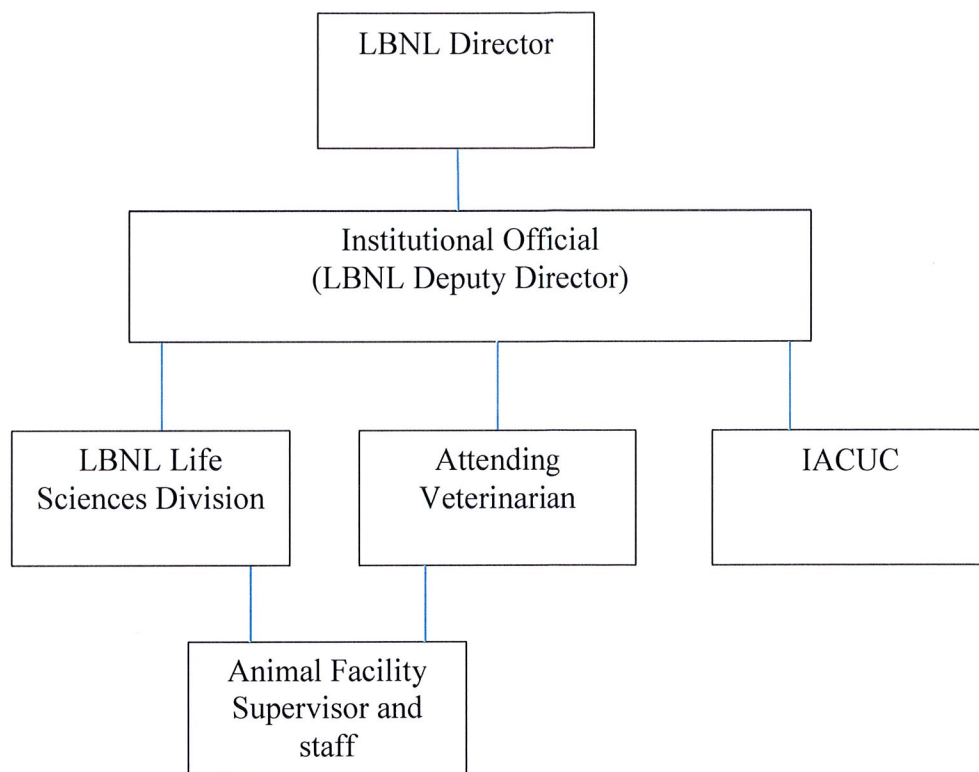
Recommended Reference:

- o [Use of the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching](#)

- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:



- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Attending Veterinarian (AV): **Nina Hahn**, DVM, MPVM, PhD, DACLAM received her DVM from the University of California, Davis School of Veterinary Medicine in 1984, is licensed to perform veterinary medicine in California and is board-certified by the American College of Laboratory Animal Medicine. She has over 25 years of experience providing veterinary care/management and regulatory oversight to academic and private research institutions. She is an independent veterinary consultant and currently serves as AV for several research institutions in the San Francisco Bay area, including Children's Hospital of Oakland Research Institute, San Francisco State University, and the California Public Health Laboratory. She is a member of the American Association of Laboratory Animal Science (AALAS) and of the Northern California Branch of AALAS and has published many papers and book chapters in the field of laboratory animal medicine.

Authority: The AV has direct program authority and responsibility for all activities involving animals at LBNL.

The AV reports to the Institutional Official and functions on behalf of the Institution to ensure and help implement a program for animal research that meets ethical and compliance standards.

Time Contributed to Program: The LBNL AV holds a 20% time position and performs routine facility visits, assists in and provides training for animal care, and holds additional consults with animal care personnel and investigators as needed. The AV works directly with the Animal Facility Supervisor to develop and implement Standard Operating Procedures to ensure ethical and efficient care and research use of animals. Dr. Hahn is on emergency call on a 24 hour/day basis.

Back-up Veterinarians: LBNL uses the University of California at Berkeley (UCB) on-call veterinary service for back-up to Dr. Hahn.

Roger A. Van Andel, D.V.M., Ph.D., (Colorado State University, 1987) PhD (University of Missouri-Columbia 1997) is currently Director of the UCB Office of Laboratory Animal care. He has 22 years of experience in laboratory animal medicine, including 20 years serving as attending veterinarian and directing programs at several academic and commercial institutions. He is board certified by the American College of Laboratory Animal Medicine and licensed to practice veterinary medicine in California.

Helen Chum, D.V.M., DACLAM, is currently a full time Attending Veterinarian at the University of California at Berkeley. She has completed a residency in laboratory animal medicine at Stanford University. Dr. Helen Chum joined the University of California, Berkeley as a clinical veterinarian in April 2014. She received her DVM from Cornell University and is licensed to practice veterinary medicine in the state of California. She worked for several years as a small animal/exotics private practice veterinarian in California before enrolling in the Stanford University residency program. She became a Diplomate of the American College of Laboratory Animal Medicine in July 2014. She is a member of AALAS, AVMA, and CLAMS.

Christie Ferrecchia D.V.M., is currently a full time Attending Veterinarian at the University of California at Berkeley. She has completed a two year residency in laboratory animal medicine at UC Berkeley and was appointed as a Campus Staff Veterinarian on May 31, 2013. She received her DVM from University of Prince Edward Island Atlantic Veterinary College in 2009; completed a residency at the Oregon National Primate Research Center, Oregon Health & Science University; and, is licensed to practice veterinary medicine in Massachusetts and Oregon. She is a member of AALAS, ASLAP, APV, AVMA, among other regional and national professional associations as well as being USDA Accredited.

- C. The LBNL IACUC (hereinafter called the Animal Welfare and Research Committee or AWRC), is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached, in part VIII, is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

The procedures and criteria for conducting the Program review are based on the sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation will include, but not necessarily be limited to, a review of the following: a) AWRC Membership and Functions; b) AWRC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); Occupational Health and Safety, and all program issues raised during convened meetings of the AWRC during the previous six months. If program deficiencies are noted during the review, they will be categorized as significant or minor and the AWRC will develop a reasonable and specific plan and proposed schedule for correcting each deficiency. The resulting written report will be discussed and voted on at a convened meeting and minority reports solicited from dissenting members. No member will be involuntarily excluded from participation in any portion of the review.

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

Inspect at least once every six months all of the institution's facilities where animals are housed or used. The Guide and other pertinent resources, e.g., the PHS Policy are used as a basis for evaluation. The AWRC or a designated subcommittee of not less than two voting members will visit each area where animals are housed or used and complete the inspection. If facility deficiencies are noted during the inspection, they will be categorized as significant or minor and the AWRC will develop a reasonable and specific plan and proposed schedule for correcting each deficiency. The resulting written report will be discussed and voted on at a convened meeting and minority reports solicited from dissenting members. All AWRC members are encouraged to participate in the Semiannual Facility Inspections. No member will be involuntarily excluded from participation in any portion of the review.

- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

A draft report based on the Program Review, facility evaluation findings, AWRC approved departures from the Guide for the Care and Use of Laboratory Animals and PHS Policy, and any additional observations submitted by members will be brought to a convened meeting of the AWRC for discussion. The draft reports will be reviewed, revised as appropriate, and approved by the AWRC. Any practice or situation found which differs from the recommendations or requirements of the PHS Policy and the "Guide," and has not been previously approved by the AWRC as an exemption from these standards, will be noted and treated as a deficiency. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan for correcting each deficiency.

Deficiencies reported from the Program Reviews and Facility Inspections are triaged into three categories based on OLAW guidance: observation, minor significance, and major significance. All findings are tracked and the individuals or parties responsible for correction and dates for correction are assigned. The final version of the findings and the corrections are approved and progress to completion is assessed by the full AWRC.

The final report will be signed by a majority of AWRC members and will include any minority opinions. If there were no minority opinions, the report will reflect this. The completed report will be submitted to the Institutional Official within 60 days following the evaluation.

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

The AWRC will review and investigate any concerns or complaints that arise involving the care and use of animals at LBNL. These include incidents reported by the Attending Veterinarian and reports of concerns by any individual to the IO, AWRC Chair, Attending Veterinarian, any member of the AWRC, or the LBNL Ombudsman. Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns. The notices will assure that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. Reporters' wishes concerning anonymity will be respected.

All reported concerns will be brought to the attention of the convened AWRC. If necessary, the AWRC Chair will convene a special meeting to discuss, investigate,

and address any reported concern. Any corrective action must either be voted on by a convened quorum of AWRC members, or, if made by the Chair or Attending Veterinarian to correct an imminent hazard, be confirmed by a convened quorum of the AWRC as soon as reasonably possible. Noncompliance, evasion or violation of the Berkeley Lab, NIH, or USDA guidelines for animal use uncovered through this process will fall under the provisions of III.D.10, below, including required reporting to the Institutional Official and OLAW.

The AWRC will review any concerns that arise involving the care and use of animals at LBNL and make recommendations to the Institutional Official when actions are required with respect to any aspect of the institution's animal program, facilities, or personnel training. Concerns raised during the semi-annual reviews will be reviewed and reported as specified in III.D.3. (above). Concerns that are raised in the periods between reviews and meriting immediate action will be reported to the Institutional Official and the Animal Facility Committee as described above for the program review and site visit (III.D.2.-3.).

- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

The IO's deputy routinely attends meetings of the AWRC and advises the IO about major concerns. If deemed necessary, the IO, the AWRC Chair and administrator, the veterinarian and the animal facilities manager, and any other appropriate personnel meet with the IO to discuss issues and problems.

- 6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

A. Meetings, Quorum, and Voting.

- a. Meetings are held monthly. If an emergency meeting is necessary to insure that the AWRC's actions conform to PHS policy, such a meeting will be called.
- b. A quorum of the AWRC is defined as a majority of the total current membership. In order for official AWRC business to be conducted, a quorum must be present.
- c. No member may participate in the AWRC approval of an application, proposal, or any animal use protocol, in which the member has a conflicting interest (e.g., is personally involved in the project), except to provide information requested by the AWRC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

B. Review of all applications and proposals involving use of animals.

1) The AWRC shall conduct a review of those sections of applications and proposals related to the care and use of animals and determine that the proposed activities are in accordance with the PHS Policy. The investigator must submit an "Animal Use Protocol" to the AWRC for each proposed experiment involving the use of animals.

New full protocols are reviewed by full committee review (FCR).

Prior to submission, all new protocols are pre-reviewed by the veterinarian.

Several days prior to every meeting, each AWRC member is provided with a copy of all proposals to be reviewed. At the meeting the AWRC votes on all protocols presented for review, selecting one of three outcomes described below.

The outcomes from FCR can be as follows:

- a. Approval. Approved protocols require no further modifications. The AWRC Chair informs the PI confirming protocol approval including the approval and expiration dates. Minor administrative changes (typos, minor grammatical errors) may be done by the Chair or AWRC Coordinator
- b. Approval denied. The PI is informed that the protocol must be resubmitted and reviewed by FCR. Suggestions are usually made to the PI and/or a recommendation is made to consult with the AV and/or Chair.
- c. Modifications are required to secure approval. Modifications to secure approval subsequent to FCR can be secured in one of two ways.
 - 1) Standard Designated Member Review (DMR). If all members are present at a meeting, modifications to secure approval may be reviewed by standard DMR. For Standard DMR process, once revisions have been submitted, the entire protocol is distributed to all AWRC members. Each member is instructed to read the protocol and agree to the DMR process, or request FCR. If after 72 hours no member has requested FCR, the Chair assigns at least two members to review the protocol.
 - 2) Special DMR (subsequent to FCR). If all members are NOT present at a meeting, modifications to secure approval subsequent to FCR may be reviewed by special DMR. The Special DMR process will be as described above for Standard DMR, except that for Special DMR (subsequent to FCR), the revised protocol is not distributed to all members, and committee members are not given 72 hours to call for FCR. Members of the AWRC have agreed at the time of the semi-annual program review was discussed in the Fall of 2014 (Oct. 15th and Nov. 19th meetings), to the Special DMR (subsequent to FCR). A written signature of all AWRC members will be collected at the program review at the monthly AWRC meeting on January 21, 2015 agreeing that a quorum of members at a convened AWRC meeting may decide to use Special DMR (DMA subsequent to FCR) to secure approval when modifications are required. The outcome of both Standard and Special DMR have two options: approval or return to FCR.

Collaborations with other institutions and organizations are submitted to the AWRC for review and approval via either DMR or FCR. These collaborative protocols include the conduct of joint research with a colleague at a different institution where some/all activities with live animals are conducted at the other institution and contracting with another institution or facility to perform specific animal research. The review ensures that the outside institution will properly house and maintain the animals, holds an approved Assurance of PHS compliance (or, for foreign institutions, equivalent protections), and that the animals were or will be manipulated under an IACUC approved protocol.

2) Prior to the review, each AWRC member shall be provided with a list of applications and proposals to be reviewed and which have been subject to non-FCR.

C. Additional approvals:

Applications and proposals that have been approved by the AWRC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve those sections of an application or proposal related to the care and use of animals if they have not been approved by the AWRC.

- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

The investigator will advise the AWRC of any proposed change or modification in an approved protocol. Such proposals will be reviewed by the AWRC at its next convened meeting. When there are significant changes, review and approval of such changes are handled in the same manner as new protocols.

Administrative review:

- 1) correction of typographical or grammatical errors
- 2) updates for researcher training in system profiles
- 3) change in personnel other than PI. All such personnel must be adequately trained and qualified, enrolled in the LBNL occupational health and safety programs, and meet other criteria as required by the AWRC.
- 4) Increase in the purchase or use of animal numbers up to 25% of approved number.
- 5) Moving requested numbers of animals predicted for use one year to a later year.

Administrative review with a veterinary consult:

- 1) Change in anesthesia, analgesia, or sedation
- 2) Change in details or method of euthanasia to any method approved by the AVMA Guidelines for the Euthanasia of Animals.
- 3) Minor procedural changes (for example: shipping animals to an NIH assured or AAALAC accredited institution; switch in source of animals which involves AWRC approved vendor; adding a new strain of mice with no change in study objectives or animal welfare implications).

Standard Designated Member Review:

The full committee is given 72 hours to review the modification and respond regarding whether or not the protocol under discussion should be reviewed by the full committee (as described above under #III.D.6).

- 1) Shipment from LBNL to a recipient without an NIH Assurance or AAALAC accreditation
- 2) Animal transportation outside of AWRC approved guidelines (for example, lab staff transportation of animals)
- 3) Change in co-PI or PI on an approved protocol
- 4) Collaborative protocols for antibody production by a PHS assured or AAALAC accredited lab, or for receiving archival or surplus tissue from a PHS assured or AAALAC accredited institution.
- 5) Collaborative protocol for antibody production by a non-PHS assured laboratory, or receiving archival or surplus tissue from a non-PHS assured institution.
- 6) Transferring animals from one AWRC approved protocol to another in cases where a relationship has not already been set up, for example, when a breeding protocol is supplying animals for an experimental protocol, and the experimental protocol lists the breeding protocol as the source of animals.

The Chair and Veterinarian can recommend any modification for DMR if both agree it is appropriate and there is a compelling need

- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The AWRC shall notify investigators and the institution in writing or via email of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure AWRC approval. If the AWRC decides to withhold approval of an application or proposal, it shall include in its written or email notification a statement of the reasons for its decision and give the investigator an opportunity to re-submit for FCR. Copies of the written notifications shall be found in the institutional online system used by the Human and Animal Regulatory Committee's office.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

The AWRC shall conduct annual reviews of each continuing protocol. Annual protocol reviews are recorded in the AWRC meeting minutes, which are reviewed and approved by the Committee. The same procedure is used for both USDA covered species and non-USDA covered species.

- Protocols are approved for a maximum of 36 months and expire no later than the three-year anniversary of the initial AWRC approval. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in III.D.6 above.
- For post approval monitoring, all protocols are subject to annual renewal.
 - a. Routine annual renewals (all protocols) are conducted by FCR and include questions about research summary, any unanticipated adverse events, numbers of animals used, if there have been any problems with performing procedure details in their full protocols, and any protocol modification.
 - b. Routine triennial renewal is conducted de novo by FCR.
 - c. The Chair and Veterinarian can recommend any annual or triennial renewal for DMR if both agree it is appropriate and there is a compelling need.

- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The AWRC may suspend an activity only after review of the matter at a convened meeting of a quorum of the AWRC and with the suspension vote of a majority of the quorum present. The report to the Institutional Official provides the results of the investigation and the recommended corrective actions as approved by AWRC.

If the AWRC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Assurance, the Institutional Official in consultation with the AWRC shall review the reasons for suspension, take appropriate corrective action and report that action with a full explanation to OLAW.

- E. The LBNL Medical Director is involved in planning and monitoring the occupational health aspects of the occupational health and safety program for personnel working in laboratory animal facilities or having frequent contact with animals. The LBNL occupational health and safety program is accredited by the Accreditation Association for Ambulatory Health Care, Inc. The program for those personnel working in laboratory animal facilities or having frequent contact with animals is based on Risk Assessment and Hazard Identification as described in the Guide for the Care and Use of Laboratory Animals. It conforms to the institutional Job Hazard Analysis program and adheres to sections of Biosafety for Medical and Biological Laboratories (BMBL) for Animal Biosafety Level 2 when applicable.

Institutional policies for personal hygiene, handling hazardous agents, and personnel protection are applicable to all aspects of animal care and handling.

The program is as follows:

1. LBNL maintains an occupational health program through the Medical Services Department of the Environment/ Health/Safety Division. For our occupational health monitoring program LBNL identifies three categories of personnel requiring such monitoring. All individuals working with access to the vivarium are included in one of these three groups. Individuals in Group 1 are all animal care workers, including the animal technicians, the animal facility manager, and the veterinarian. Group 2 is made up of the animal care researchers, the scientists and laboratory technicians with access to the vivarium. Group 3 encompasses the animal care facilities personnel, such as electricians, plumbers, and general physical plant maintenance workers. Group 1 is required to have a mandatory physical exam every two years and sent an animal questionnaire enquiring about their exposure to animals, any physical symptoms they may be exhibiting, etc. Group 2 is sent the animal questionnaire annually and voluntary physical exams are available to members of this group. Members of Group 3 are also sent the annual animal questionnaire and also have physical exams available to them upon request. These physical examinations include a review of medical history, tuberculosis testing, and the need for individual preventive medical measures such as vaccinations, allergen exposure prevention, and/or special precautions related to preexisting conditions.
2. Staff members entering facilities within the animal colony are required to use personnel protection equipment (PPE --lab coats, scrub suits, gowns, masks, shoe covers and head gear) for their own health protection as well as that of the animals. The PPE requirements are specific to each facility: current holding areas for a mouse breeding and maintenance facility, cage washing and sterilizer room, experimental areas for mice, rats, zebrafish, and larger animal imaging.
3. Other health and safety issues such as safety training and awareness, personal hygiene, risk identification and alleviation, and injury/illness reporting requirements are covered by LBNL's Health and Safety Manual that applies to all staff on-site. Our attending veterinarian and the animal facilities manager provide training to LBNL staff on potential zoonotic diseases, development of allergies to laboratory animals, and the hazards associated with handling laboratory animals as well as working in an animal facility. The LBNL Medical Director routinely screens for all positions at LBNL where immunosuppression could constitute a personal health risk.
4. Vaccination for tetanus is required for all Berkeley Lab animal care personnel at hiring and at 10-year intervals thereafter. Vaccination for tetanus is also available to all research personnel handling animals, and investigators are encouraged to institute a tetanus program for their staff members likely to handle animals.
5. Instructions for immediate treatment for bites and scratches is provided in the Animal Care Facility Animal Biosafety Manual, the Medical Imaging Biosafety Manual, and in Standard Operating Procedures specific to the appropriate facility(ies). Follow-up first aid for minor injuries is provided in the LBNL Medical Clinic. Serious or life-threatening injuries would be referred immediately to the local trauma center at Alta Bates Hospital in Berkeley.
6. Staff members coming into contact with primates are required to have a skin test for tuberculosis annually. (Although no primates are housed on site, primates occasionally are brought to Berkeley Lab for imaging studies. See item 7 below and the Facilities and Species Inventory for more information.)

7. Screening tests for intestinal parasites and bacterial infections are conducted on staff handling primates when deemed necessary or on request.
 8. The facility at LBNL which handles nonhuman primates, the Animal Imaging Facility (AIF), is covered by a Manual based on the BMBL. This Manual contains the Standard Operating Procedures of the University of California at San Francisco (UCSF) Primate Facility. These SOPs include medical surveillance and screening policies and procedures as well as on-site bite and scratch treatment. A treatment protocol for nonhuman primate bites has been established and is posted in any Lab facility where contact with nonhuman primates may occur. There are bite kits and first aid kits at hand in the AIF. The AIF operates under a Biosafety Use Authorized (BUA) from the LBNL Institutional Biosafety Committee (IBC). The nonhuman primate handlers are exclusively UCSF Primate Colony Staff. Their training is verified as part of the approval process for LBNL Animal Use Protocol. The UCSF Animal Colony is AAALAC accredited and their last site inspection included the AIF at LBNL. In more than two years there have been no nonhuman primates imaged at the AIF. At the time of the Semiannual Facility inspections by the AWRC, the AWRC administrator queries the AIF staff on any anticipated animal use for the next six months. When none is reported, the AIF staff are reminded that the AWRC administrator must be notified well in advance when nonhuman primates will be coming to the facility so that the AWRC may conduct a site inspection prior to the nonhuman primates arrival.
 9. The program for reporting injuries or disease possibly arising from animal care and handling or as a result of work activities in animal facilities is to report them immediately to Medical Services in compliance with LBNL institutional policies and procedures for such reporting. Additionally, any primate-related injury must be reported to UCSF at the number provided in the Manual and posted in the facility.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.
See section X below.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:
The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows: All individuals performing research related activities on animals at LBNL must be adequately trained to do so.

Training available to all personnel involved in animal care, treatment and use:

- a. All personnel involved in animal use and care must complete the "Working with the IACUC" module available from the AALAS Learning Library. Completion of training is documented by AWRC office staff and must be repeated every three years. This training includes discussion of animal welfare regulations and principles including methods that minimize pain and distress and minimizing the number of animals to that required to achieve valid experimental results.
- b. New staff members who will be handling animals must receive an orientation on the Berkeley Lab animal colony and the AWRC Guidelines for Users of the LBNL Animal Colony from the animal facilities manager. During
- c. AALAS certification classes (ALAT, LAT or LATG) are provided every 2-3 years for animal care staff. Researchers and staff are encouraged to take these classes as well.
- d. Animal User Group meetings are held periodically to inform users about updated policies and to provide an open forum to ask questions to attending veterinarian, animal facility manager, AWRC staff and AWRC chair.
- e. The attending veterinarian and animal facility manager will train personnel in small groups or one-on-one on specific procedures and methods.


- f. Euthanasia training and certification (by the ACF manager) is mandatory.
- g. Surgical training and certification (by the AV) is mandatory.

AWRC member training:

- a. All personnel involved in animal use and care must complete the "Working with the IACUC" module available from the AALAS Learning Library. Completion of training is documented by IACUC office staff and must be repeated every three years.
- b. AWRC members are provided with copies of or otherwise have access to the PHS policy, the Guide for the Care and Use of Laboratory Animals, the OLAW/ARENA IACUC Guidebook and a copy of the approved Animal Welfare Assurance.
- c. Continuing training takes place at the Full Committee Meeting when necessary.
- d. AWRC members are encouraged to attend AALAS, AAALAC, OLAW, etc. webinars, seminars or conferences.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

- (1) This Institution is Category 1 — accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#) . As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years:
 - 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
 - 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
 - 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
 - 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Horst Simon.
 - 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The AWRC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
 - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
 - 3. Any change in the IACUC membership
 - 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Horst Simon.
 - 5. Any minority views filed by members of the IACUC
- B. The AWRC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 - 1. Any serious or continuing noncompliance with the PHS Policy
 - 2. Any serious deviations from the provisions of the *Guide*
 - 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above include any minority views filed by members of the AWRC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: Horst Simon, PhD

Title: Berkeley Lab Deputy Director

Name of Institution: Lawrence Berkeley National Laboratory

Address: *(street, city, state, country, postal code)*

Laboratory Directorate

Lawrence Berkeley National Laboratory

1 Cyclotron Road, MS 50A4119

Berkeley, CA 94720

Phone: 510/486-6100

Fax: 510/486-6720

E-mail: HDSimon@lbl.gov

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

Signature:



Date:

January 12, 2015

B. PHS Approving Official *(to be completed by OLAW)*

Name/Title:

Office of Laboratory Animal Welfare (OLAW)

National Institutes of Health

6705 Rockledge Drive

RKL1, Suite 360, MSC 7982

Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817)

Phone: +1 (301) 496-7163

Fax: +1 (301) 915-9465

Signature:

Date:

Assurance Number:

Effective Date:

Expiration Date:

VIII. Membership of the IACUC

Date: 7/23/2014

Name of Institution: Lawrence Berkeley National Laboratory

Assurance Number: A 3054-01

IACUC Chairperson

Name*: Antoine Snijders

Title*: Senior Staff Scientist

Degree/Credentials*: PhD

Address*: (street, city, state, zip code)

Animal Welfare and Research Committee

Lawrence Berkeley National Laboratory

1 Cyclotron Road, MS 64-0121

Berkeley, CA 94720

E-mail*: amsnijders@lbl.gov

Phone*: 510/486-7235

Fax*: 510/486-6691

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Antoine Snijders	PhD	Senior Staff Scientist	Chairperson, Scientist
2	PhD	Senior Staff Scientist	Vice Chair, Scientist
Nina Hahn	DVM, PhD	Attending Veterinarian	Veterinarian
4	PhD	Senior Staff Scientist	Scientist
5	PhD	Staff Scientist	Scientist
6	MS	Biosafety expert	
7	PhD	Staff Scientist	Scientist Alternate
8	BS	Lay religious leader, QA specialist	Community member, Nonaffiliated
9	MVZ	Animal Colony Manager	
10	MA (Biology)	Compliance Specialist	Nonscientist
11	PhD (Anthropology)	Compliance Specialist	Nonscientist

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* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** [PHS Policy](#) Membership Requirements:

<i>Veterinarian</i>	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name: Dianna Bolt	
Title: AWRC (IACUC) Coordinator	
Phone: 510/486-6005	E-mail: dgbolt@lbl.gov
Contact #2	
Name: Chris Byrne	
Title: IRB Administrator, back-up IACUC coordinator	
Phone: 510/486-5507	E-mail: cebyrne@lbl.gov

X. Facility and Species Inventory

Date: August 7, 2014

Name of Institution: Lawrence Berkeley National Laboratory

Assurance Number: A 3054-01

Laboratory, Unit, or Building*	Gross Square Feet [<i>include service areas</i>]	Species Housed [<i>use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog</i>]	Approximate Average Daily Inventory
B 86	4800	Mice	3500 mice
B 977	3400	Mice Rats	2150 mice 135 rats
B 70A	600	Mice	230 mice

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.